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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,575	04/13/2001	Arthur Lander	82351.0003	9101

34284 7590 03/23/2006

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,575	LANDER ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/22/02*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1-12 are pending.

Claims 1, 5 and 6 have been amended.

Claims 7-12, drawn to non-elected inventions are withdrawn from examination.

Claims 1-6 are examined on the merits to the extent the binding molecule bind to glypican-1.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objection

Claim Objections

3. The objection of claim 5 is withdrawn in light of the amendment to the said claim, wherein "glypican-1" has been properly cited, see amended claims submitted December 22, 2005.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendments.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994) is withdrawn in light of the claim amendments. conclude that the disclosed antibody would detect glypican-1 in a body fluid.

6. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997) is withdrawn in light of the claim amendments.

7. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997) is withdrawn in light of the claim amendments.

8. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87, January 1998) is withdrawn in light of the claim amendments.

9. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998) is withdrawn in light of claim amendments.

Maintained Objection

Claim Objections

10. The objection of claims 1, 3 and 4 is maintained and made because claims 1, 3 and 4 continue to reference non-elected subject matter, namely binding molecules or antibodies that bind syndecan-1. Applicants note the objection is moot because of claim amendments submitted December 22, 2005, however claims 1, 3 and 5 have not been amended to remove syndecan-1.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

11. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998).

Applicants argue amendments to claim 1 and the preamble requires the diagnostic agent to detect breast or pancreatic cancer, see Remarks, bridging paragraph of pages 4 and 5. Applicants note Karthikeyan describes composition and methods for detection of rat glypican in various non-cancerous neuronal tissues, which is, in contrast to Applicants' claimed method. These points of view have been carefully considered, but found unpersuasive.

Applicants' preamble reads on intended use, which does not have patentable weight. The anti-glypican antibody disclosed by Karthikeyan would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat

glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Karthikeyan discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 3213, "Preparation of antibodies..." section, first sentence. Attached to the said antibody was a peroxidase-conjugated goat anti-rabbit IgG, thereby aiding in imaging, see page 3216, column 1, paragraph before "In situ..." section and Figure 5. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid.

Moreover, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

12. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998).

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

Applicants' preamble reads on intended use, which does not have patentable weight. The anti-glypican antibody disclosed by Ivins would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Ivins discloses 343-1, an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 321, "Antipeptides..." section, last sentence. Attached to the said antibody was a Cy3-conjugated goat anti-rabbit antibody for immunofluorescence, thereby aiding in imaging, see page 325, paragraph before "Proteoglycan..." section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid.

Moreover, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

13. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998).

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

Applicants' preamble reads on intended use, which does not have patentable weight. The anti-glypican antibody disclosed by Liang would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Liang discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 852, "Antibodies..." section, first sentence. Attached to the said antibody was a peroxidase-conjugated goat anti-rabbit IgG, thereby aiding in imaging, see page 852, "Electrophoresis..." section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid.

Moreover, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

14. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998).

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

Applicants' preamble reads on intended use, which does not have patentable weight. The anti-glypican antibody disclosed by Litwack would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Litwack discloses 343-1, an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 77, "Expression..." section and page 85, "Anti-Peptide Antibodies" section. Attached to the said antibody was a Cy3-conjugated goat anti-rabbit antibody, thereby aiding in imaging, see page 85, "Immunohistochemistry" section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid.

Moreover, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant

discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

15. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998).

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

Applicants' preamble reads on intended use, which does not have patentable weight. The anti-glypican antibody disclosed by Liu would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Liu discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 22829, Figure 5 and the first paragraph of the "Characterization..." section. Attached to the said antibody was a biotinylated goat anti-rabbit IgG, thereby aiding in imaging, see page 22827, last two sentences of the "Western Blotting" section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid.

Moreover, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
20 March 2006